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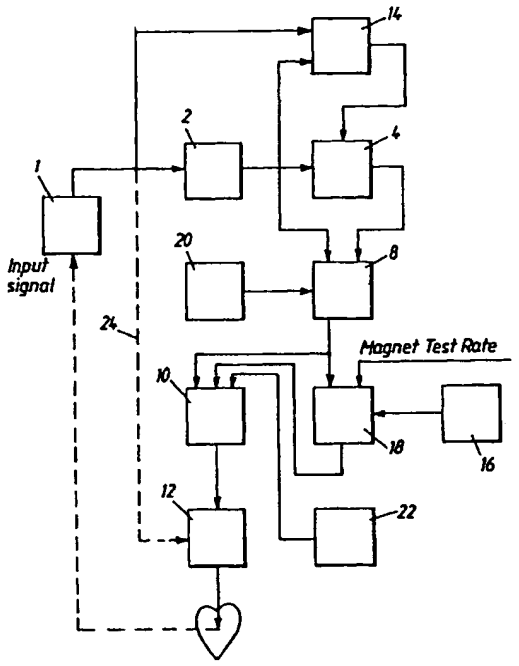
(54) Interference detecting pacemaker

(57) A pacemaker comprises an interference detecting circuit (2), and an evaluating and storing means (4) for continuously evaluating and storing the heart rate. The evaluating and storing means is adapted to store the rate evaluated from at least one of the latest cardiac cycles free of interference. A determining means (8) is provided for determining an interference backup rate from the stored rate in response to the detection of the onset of an interference situation. A control means (9) is provided to then adjust the pacing rate equal to said interference backup rate.

Fig.1



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Description

Technical Field

[0001] The present invention relates to a pacemaker comprising an interference detecting circuit and an evaluating and storing means for continuously evaluating and storing the heart rate.

Background to the Invention

[0002] It is previously known to devise pacemakers such that they in an interference situation revert to an "interference backup pacing" with a pacing rate equal to the programmed basic rate or equal to a predetermined rate which is somewhat higher than the programmed basic rate. Thus in US-A-4,091,818 a cardiac pacing apparatus is described having a first signal processing channel which functions in the demand mode and a second signal processing channel for detecting electromagnetic interference and causing the pacing apparatus to revert to a safe operating rate in the presence of such interference. This operating rate may be an appropriate predetermined fixed rate or a rate-limited rate synchronous with the detected electromagnetic interference.

[0003] Also US-A-5,522,857 discloses a pacemaker with a means for determining when the sensed signals indicate depolarisation signals from the patient's heart and when such sensed signals are noise signals and cannot be used for control of the pacemaker. Safety means are provided for controlling the pulse generator to generate a pace pulse in response to a noise determination that occurs after time out of a predetermined time interval.

[0004] From EP-A-0 713 714 a control system for medical devices is previously known in which electromagnetic interference of a biomedical signal used for the control of the device is determined with the aid of a correlator. The device is operated in normal manner as long as the intensity or level of the electromagnetic interference component is such that it does not affect or interfere with the device operation. When the level of the electromagnetic interference passes a predetermined threshold the biomedical signal is blanked and a replacement signal derived from either a previous normal input signal, a stored signal, or synthesized signal is substituted for the biomedical signal.

[0005] US-A-4,516 579 discloses an interference recognition circuit in a heart pacemaker for improved recognition of certain kinds of interference. The circuit is used for testing sensed heart action signals to recognize the signal as an interfering signal and then rendering the signal ineffective , or recognizing the signal as a true heart action signal and then feeding the signal to a control circuit for the pacemaker.

[0006] The backup pacing according to the prior art in interference situations is normally performed at fixed rate and asynchronously to the patient's intrinsic heart activity. Thus the backup pacing is not adapted to the patient's physiological means.

[0007] Thus, if a patient has e.g. a VVI-pacemaker programmed to a basic rate of 70 bpm and at a given time has an intrinsic heart rate of 85 bpm, the pacemaker will operate in inhibited mode. When this patient enters into a strong electromagnetic field, e.g. of certain types of anti-theft systems in departmental stores or of any other strong interference sources, the pacemaker will not be able to discriminate intrinsic heart activity due to the electromagnetic interference voltages induced in the electrode, but will instead detect the electromagnetic interference during noise sample window and change mode of operation to asynchronous VOO-pacing at e.g. 70 bpm. These pacing pulses at the rate of 70 bpm can stimulate within the vulnerable phase of the EGM and induce fibrillation to the patient's heart. A number of cases have been reported in literature where competitive fixed rate pacing introduced cardiac fibrillation. The same may happen to patients entering a static magnetic field which closes the reed-switch or equivalent means inside the pacemaker with the result that the pacemaker reverts to fixed magnetic test rate pacing.

[0008] Different inductive loop applications, like e.g. electronic article surveillance (EAS) systems, are expected to increase very rapidly in the near future, and even if heart signal detection and discrimination in implanted heart stimulators will become more sophisticated the number of interference situations will increase. This expected development requires a much more sophisticated technique or interference backup pacing in the future, which will decrease the risk of induced fibrillation to the patient's heart.

[0009] Therefore, it is the purpose of the present invention to propose a new pacemaker which, whenever it experiences such a high level of electromagnetic inference that it becomes unable to sense the intrinsic heart activity, reverts to defined interference operation in a safe way and is stimulating with a pacing rate which is well adapted to the patient's intrinsic heart rate or the pacing rate prior to the onset of the interference.

[0010] Certain rate responsive pacemakers in the art have a feature allowing them, during interference situations, to continue pacing in a sensor controlled rate and therefore should it be noted that the pacemaker according to the invention is particularly useful in non rate responsive pacemakers.

Summary of the Invention

[0011] This purpose is obtained by a pacemaker according to the introductory portion of the description with the characterizing features of claim 1.

[0012] With the pacemaker according to the invention is thus during interference situations a pacing rate provided to the patient which is well adapted to the specific needs of the patient through continuous evaluation,

storage and determination of a proper interference backup rate or proper interference backup interval prior to the occurrence of interference. In this way the number of induced ventricular fibrillation to the patient due to asynchronous fixed rate interference pacing can be considerably reduced or totally eliminated. The pacemaker according to the invention can be a single as well as a dual chamber pacemaker with unipolar or bipolar electrode configurations.

[0013] The improved interference backup pacing of the pacemaker according to the invention can be programmed and tailored to particular needs. For certain pacemaker patients, e.g. those suffering from AV block III it is not meaningful to evaluate QRS-QRS intervals. In this case it is appropriate, at the onset of an interference situation, to continue to stimulate at a pacing rate which is equal to the latest pacing rate before the onset of the interference.

[0014] According to an advantageous embodiment of a pacemaker according to the invention said evaluating and storing means is adapted to store the rate evaluated from a predetermined number of the latest cardiac cycle. Thus by calculating the rate during e.g. the latest 4-8 pacing cycles without interference and storing this rate the pacemaker can always be ready for providing asynchronous fixed rate pacing pulses at a suitable rate for the particular patient at a sudden onset of an interference situation.

[0015] According to another advantageous embodiment of the pacemaker according to the invention said determining means is adapted to determine said interference backup rate equal to a rate which is somewhat higher than the average value of the heart rate during said plurality of cardiac cycles. During interference backup pacing the pacing rate shall preferably be e.g. 10 % higher than the observed intrinsic pacing rate or the actual pacing rate or rate responsive pacing rate during the latest 4-8 cardiac cycles.

Brief Description of the Drawings

[0016] To explain the invention in greater detail embodiments of the pacemaker according to the invention, chosen as an example, will now be described with reference to the enclosed drawings, on which figure 1 shows a block diagram of an embodiment of the pacemaker according to the invention, and figure 2 shows different signals as a function of time for a normally inhibited pacemaker devised according to the invention.

Description of Preferred Embodiments

[0017] The pacemaker according to the invention comprises an interference detecting circuit 2 to which a cardiac input signal is supplied via an input filter and detector circuit 1. To the interference detecting circuit 2 an evaluating and storing means 4 are connected for continuously evaluating the heart rate from the input signal and storing this heart rate.

[0018] A determining means 8 is connected to the outputs from the evaluating and storing means 4 and from the interference detecting circuit 2 for determining an interference backup rate from the stored heart rates in response to the detection of the onset of an interference situation. The calculated interference backup rate is then supplied to a control means 10 which is connected to the pulse generator 12 of the pacemaker for adjusting the pacing rate equal to the determined interference backup rate.

[0019] As an alternative the determining means 8 can be adapted to determine or calculate an interference backup rate prior to any occurrence of interference and storing this determined backup rate value to be used at the detection of the onset of an interference situation.

[0020] The input signal is also supplied to a cardiac cycle determining and counting means 14, which is also connected to the output of the interference detecting circuit 2 for determining and counting cardiac cycles without interference. The determining and counting means 14 is controlling the storing of the heart rate in the evaluating and storing means 4 such that heart rates are determined and stored during a predetermined number of pacing cycles, e.g. 4-8 pacing cycles, without interference, for the interference backup rate determination. In this way the pacemaker is always ready for providing asynchronous, fixed rate pacing pulses at a suitable rate for a particular patient at a sudden onset of an interference situation.

[0021] The determining and counting means 14 is preferably adapted to control the evaluating and storing means 4 such that the evaluated heart rate from the very last cardiac cycle before a detected onset of an interference situation is disregarded. This is a safety measure for securing that the calculated interference backup rate in a reliable way will be very well adapted to the patient's actual need at the time of an onset of interference.

[0022] The determining means 8 is preferable adapted to determine the interference backup rate somewhat higher, e.g. 10% higher, compared to the observed intrinsic or pacing rate. Thus in an interference situation the actual pacing rate is somewhat higher than the observed heart rate before the interference situation.

[0023] If intrinsic heart activity is present, and the pacemaker is inhibited, the shortest interval, from QRS to QRS or P-pulse to QRS shall be considered when determining the interference backup rate.

[0024] Onset of interference is detected in the interference detecting circuit by use of noise sample windows according to previously known technique.

[0025] If a patient is exposed to a static magnetic field which closes the reed-switch or an equivalent field sensing component, e.g. hall element, telemetry coil, magnetoresistor, etc., of the pacemaker, a transition to asynchronous magnetic test rate shall be performed

only if actual magnet test rate (battery test) is higher than the interference backup rate. A sensing means 16 is therefore provided to sense closure of the reed-switch and to control a comparator 18 to compare the determined interference backup rate with the predetermined magnet test rate. Transition to magnet test rate then takes place if the test rate exceeds the determined interference backup rate. This feature of the pacemaker according to the invention is preferably programmable such that this function can be switched off by the physician if it is not desired for a specific patient.

[0026] A marker function could also be provided for the case with the magnet test rate being lower than the interference backup rate. In the simplest form the marker can consist of e.g. one P-pulse (pacing pulse) synchronous with a detected heart signal (QRS) in case of spontaneous heart activity and in response to application of a magnet. The purpose of this marker function is to make the physician, who wants to perform a magnet test, aware of the fact that the battery test-rate is lower than the calculated interference backup rate. This marker is seen on a surface ECG, but could of course be of other kinds as well, e.g. one 'double' pacing pulse, i.e. two pulses with a short coupling interval of the order of 50 - 100 msec. The same type of marker, which appears on surface ECG:s, can be provided also in the case when the stimulation rate prior to the application of the magnet is higher than the battery test rate.

[0027] The interference backup rate must be within certain predetermined limits, e.g. always less than 160 bpm, and therefore a limiting means 20 is connected to the determining means 8 for setting the allowed limits for the interference backup rate.

[0028] A workload sensor 22 or another physiological rate response sensor is controlling the stimulation pulse generator 12 to adapt the stimulation rate to the patient's physiological needs.

[0029] In ordinary pacing mode the pacing rate is determined by the heart rate detected from the input signal. This relation is indicated by the dashed line 24.

[0030] Additional means of the pacemaker, such as power supply, additional electronics, reed-switch as mentioned above, telemetry means etc. are not shown in the block diagram to simplify the figure 1, since these means do not directly form any part of the invention.

[0031] The operation of a normally inhibited pacemaker designed according to the invention will now be explained with reference to figure 2 which shows different signals as a function of time.

[0032] Curve a in figure 2 thus shows spontaneous heart activity QRS and a period of interference, and curve b the corresponding detected QRS and interference signals. Curve c shows a signal switching between two levels representing normal inhibited operation of the pacemaker according to the invention and an interference mode of operation. Curve d illustrates the time lapse of the number of counts of a counter for determining the programmed basic rate interval of the pacemaker and curve e illustrates the corresponding time lapse for a counter for determining the interference backup interval. Curve f shows stimulation pulses delivered by the pacemaker.

[0033] Figure 2 first illustrates a situation of spontaneous heart activity. Thus QRS complexes are regularly occurring, see curve a, and corresponding signal pulses are detected, see curve b. Each time a QRS complex appears the counter determining the basic rate interval is reset, see curve d. This takes place before the programmed time out (T.O.) of the basic rate interval counter. Thus, the spontaneous heart rate of the patient is higher than the programmed basic rate and the pacemaker operates in inhibited mode as appears from curve f.

[0034] Also the interference backup interval counter is reset by the QRS complexes, see curve e. Thus, in this situation the interference backup interval is determined by the QRS-QRS interval.

[0035] The interference backup counter is devised to determine an interference backup interval, which is somewhat shorter than the basic rate interval, i.e. the interference backup rate is chosen somewhat higher than the basic heart rate. The interference backup rate can be e.g. 10% higher than the basic rate as mentioned above. In the shown situation the interference backup rate is also somewhat higher than the spontaneous heart activity, and consequently the interference backup interval counter will time out in the period between two consecutive QRS complexes, which appears as a constant level T.O. of a certain extension in curve e immediately before the reset of the interference backup counter.

[0036] At a certain time an interference situation starts, see curve a, and an interference mode is detected by the interference detecting circuit, cf. curve c in figure 2. In an interference situation possible spontaneous activity of the heart cannot be reliably detected and the operation of the basic rate interval counter is stopped at a certain level. The timing of the pacemaker is then controlled by the interference backup interval and in this mode of operation stimulation pulses are delivered at each time out T.O. of the interference backup counter as shown by curve f. Corresponding evoked responses ER appear in curve a.

[0037] After termination of the interference state the basic rate interval counter will start operation again after a predetermined period provided that no interference is detected in this period, cf. curves c and d, and the mode of operation free of interference described earlier is resumed.

[0038] Figure 2 illustrates a situation just comprising spontaneous heart activity and periods of interference. Of course also other situations of cardiac pacing can be managed by the pacemaker according to the invention.

Claims

1. A pacemaker comprising an interference detecting circuit (2) and an evaluating and storing means (4) for continuously evaluating and storing the heart rate, **characterized in** that said evaluating and storing means (4) is adapted to store the rate evaluated from at least one of the latest cardiac cycles free of interference, and in that a determining means (8) is provided for determining an interference backup rate from said stored rate in response to the detection of the onset of an interference situation, a control means (10) being provided to then adjust the pacing rate equal to said interference backup rate.

2. The pacemaker according to claim 1, **characterized in** that a cardiac cycle determining and counting means (14) is provided to control said evaluating and storing means (4) to store the rate evaluated from a predetermined plurality of the latest cardiac cycles.

3. The pacemaker according to claims 1 or 2, **characterized in** that said evaluating and storing means (4) is adapted to disregard, in the rate evaluation, the very last cardiac cycle before a detected onset of an interference situation.

4. The pacemaker according to any of the preceding claims, **characterized in** that said determining means (8) is adapted to determine said interference backup rate equal to a rate which is somewhat higher than the average value of the heart rate during said plurality of cardiac cycles.

5. The pacemaker according to any of the preceding claims, **characterized in** that a sensor (22) is provided for sensing the workload of the patient and controlling the pacing rate in response thereto.

6. The pacemaker according to any of the preceding claims, **characterized in** that a limiting means (20) is connected to said determining means (8) for setting an upper limit for the interference backup rate.

7. The pacemaker according to any of the preceding claims, **characterized in** that a sensing means (16) for sensing closure of a reed-switch or another field sensing component is provided to control a comparator (18) to compare the stored evaluated rate with a preset magnet test rate in response to the closure of said reed-switch or other field sensing component, and in that said comparator is controlling said control means (10) to adjust the pacing rate equal to said magnet test rate only if the magnet test rate is higher than the stored rate.

Fig.1

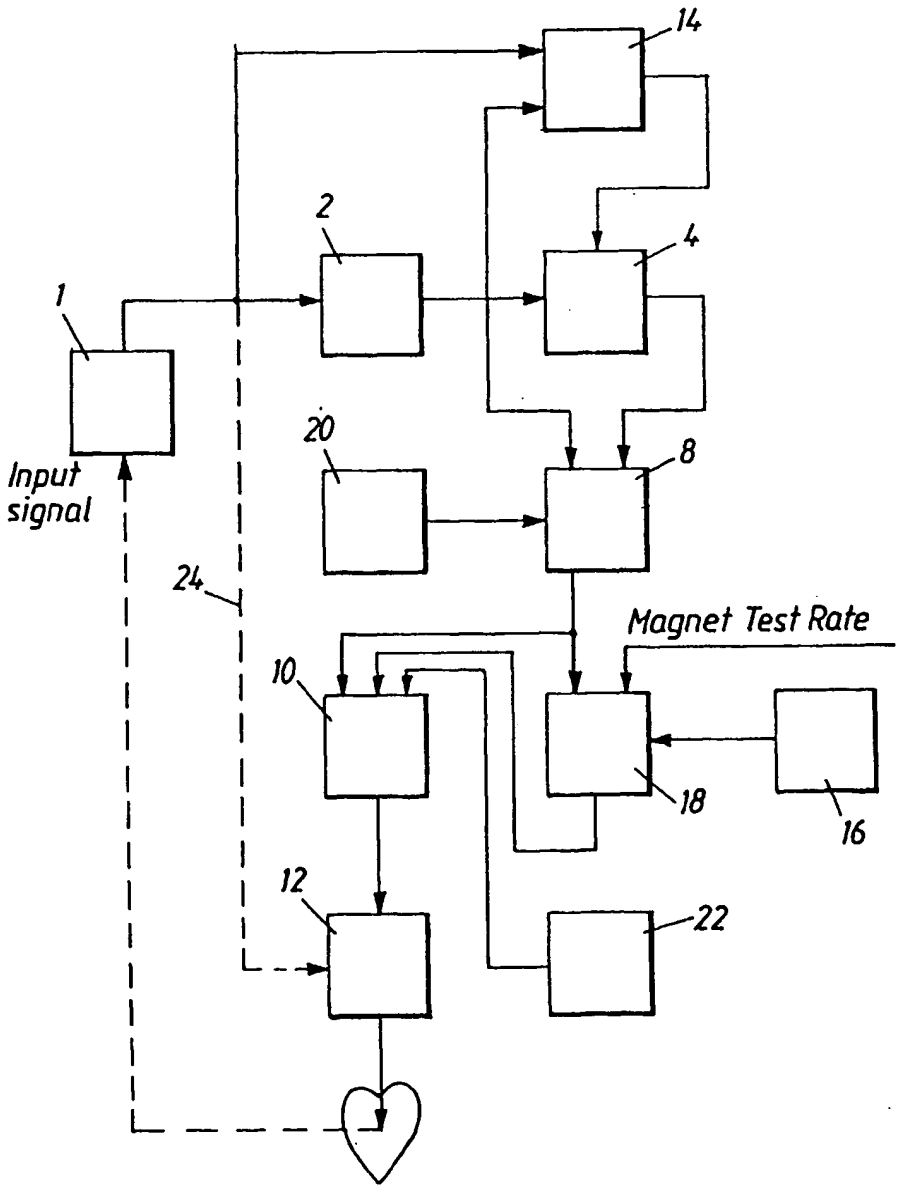

Fig. 2

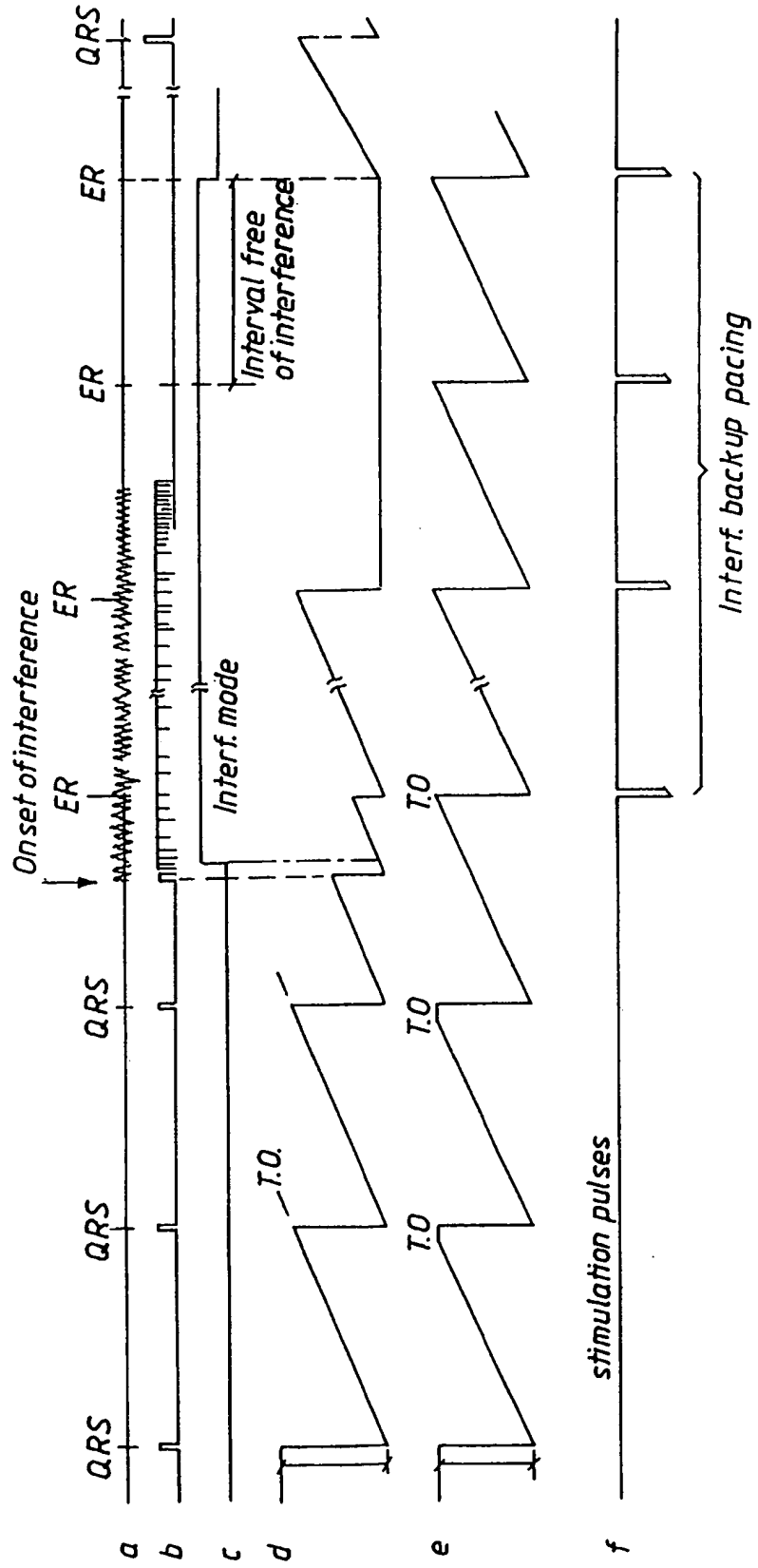
QRS
QRS
QRS
ER
ER
ER
QRS
Onset of interference
Interf. mode
Interval free of interference
T.O.
T.O
T.O
T.O
stimulation pulses
Interf. backup pacing
a
b
c
d
e
f

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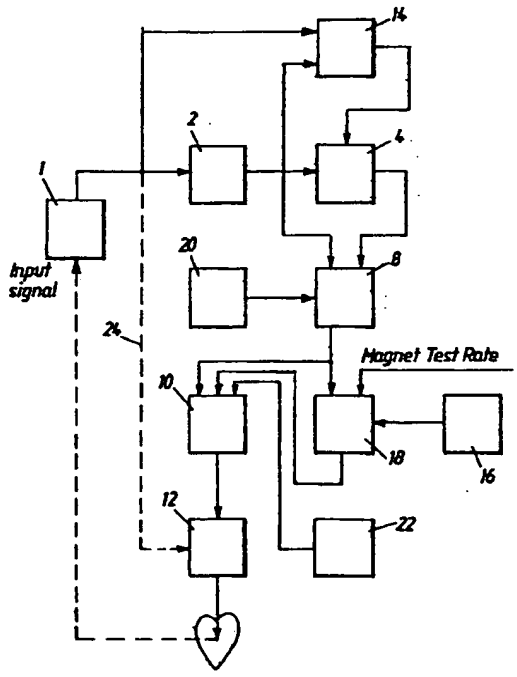
Fig.1



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EUROPEAN SEARCH REPORT

Application Number
EP 98 12 1618.7

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
A	EP 0707866 A2 (VITATRON MEDICAL B.V.), 24 April 1996 (24.04.96) * see the whole document * --	1-7	A61N 1/365 A61N 1/37
D,A	EP 0713714 A2 (VENTRITEX, INC.), 29 May 1996 (29.05.96) * see the whole document * --	1-7	
D,A	US 5522857 A (F.M. VAN KRIEKEN), 4 June 1996 (04.06.96) * see the whole document * --	,1-7	
A	US 3661157 A (J.W. FYSON E TAL.), 9 May 1972 (09.05.72) * see the whole document * -----	1-7	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	12 May 1999	PATRIK BLIDEFALK/AE

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 5522857 A	04/06/96
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US 3661157 A	09/05/72	NONE	

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